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EXAMINER	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/939,239
Filing Date: August 24, 2001
Appellant(s): WALKER ET AL.

John Rogitz
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 02/10/05 appealing from the Office action mailed 1/26/05.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

4,941,475	Williams et al.	7-1990
6,117,105	Bresnaham et al.	9-2000
6,110,139	Loubser	8-2000

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 5-8, are rejected under 35 U.S.C. 102(b) as being anticipated by Williams et al. (USPN 4,941,475).

Williams et al. discloses a venous line catheter with at least one elongate structure for establishing central venous access, wherein the catheter has a distal and proximal end and a lumen in communication with the exterior of the elongated structure at said proximal and distal portions, and at least one heat exchange element and a pump (Figures 1, 3, 7 and entire reference).

Williams et al. further discloses wherein the heat exchange element is made of urethane, nylon, PE or PET, and the heat exchange is a balloon (Figures 1, 3, 7 and entire reference).

Claims 5-8, are rejected under 35 U.S.C. 102(e) as being anticipated by Bresnaham et al. (USPN 6,117,105).

Bresnaham et al. discloses a venous line catheter with at least one elongate structure for establishing central venous access, wherein the catheter has a distal and proximal end and a lumen in communication with the exterior of the elongated structure at said proximal and distal portions, and at least one heat exchange element and a pump (Figures 14, 30 and entire reference).

Bresnaham further discloses wherein the heat exchange element is made of urethane, nylon, PE or PET, and the heat exchange is a plurality of balloons (Figures 14, 30 and entire reference).

Claims 5-8, 22-27, 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams et al. as applied to the claims above, and further in view of Loubser (USPN 6,110,139).

Williams et al. teaches the claimed invention but fails to disclose the specific range in which the pump is used.

Loubser discloses a perfusion pump that has a flow rate of about 240 milliliters per minute (Column 12, lines 1-26).

At the time of the invention it would have been obvious to use the pump of Williams et al. at the specific range that is taught by Loubser because Williams et al. has the same type of pump, and it is well known in the medical art as shown by Loubser to use a perfusion pump with a flow rate at 240 milliliters per minute to allow medicament or other liquids to be entered into the human body at the specific range. The examiner would also like to note that since Williams et al. discloses the same type of pump, the examiner determined that the pump of Williams would be capable of having a flow rate about 240 milliliters, since the Loubser reference disclosed the same pump, and how this pump has a flow rate within the range that is being claimed. Therefore, the examiner determines that the pump of Williams et al. is capable of pumping fluid at the rate that is being claimed in this invention when Williams et al. is considered in view of Loubser.

Claims 5-8, 22-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bresnaham et al. as applied to the claims above, and further in view of Loubser (USPN 6,110,139).

Bresnaham et al. teaches the claimed invention but fails to disclose the specific range in which the pump is used.

Loubser discloses a perfusion pump that has a flow rate of about 240 milliliters per minute (Column 12, lines 1-26).

At the time of the invention it would have been obvious to use the pump of Bresnaham et al. at the specific range that is taught by Loubser because Bresnaham et al has the same type of pump, and it is well known in the medical art as shown by Loubser to use a perfusion pump with a flow rate at 240 milliliters per minute to allow medicament or other liquids to be entered into the human body at the specific range. The examiner would also like to note that since Bresnaham et al. discloses the same type of pump, the examiner determined that the pump of Bresnaham would be capable of having a flow rate about 240 milliliters, since the Loubser reference disclosed the same pump, and how this pump has a flow rate within the range that is being claimed. Therefore, the examiner determines that the pump of Bresnaham et al. is capable of pumping fluid at the rate that is being claimed in this invention when Bresnaham et al. is considered in view of Loubser.

(10) Response to Argument

The examiner disagrees with the arguments set forth in the brief.

The first argument is drawn to the language of "central venous line catheter" which the examiner interprets to be intended use in the preamble. The applicant never recites any limitations to the size, or shape of the catheter, but in dependent claims discusses the length of the catheter, and the size of the balloons of the catheter, which never explicitly limits the size or shape of the catheter in the claims. Therefore the examiner interpreted the prior art to be capable of being put into the jugular vein because the examiner interpretation of "central venous line catheter" in the preamble with no other limitations drawn to the size of the catheter is a broad interpretation since the size of a central venous vessel can vary significantly from person to person, or more specifically from a baby to a male adult. Thus the examiner determines that the catheter of the prior art would be capable of being inserted or at least partially inserted into the largest vein in an adult male's body therefore meeting the claim limitations.

The next issue that the examiner disagrees with the applicant on; deals with the interpretation of the limitation "manufactured by flushing the first lumen from its distal portion to its proximal portion with sterile saline." The examiner interprets this limitation to be a clear product by process limitation, therefore when dealing with a product by process limitation the end product is used for determining patentability unless applicant comes forward with evidence proving otherwise. The applicant failed to do that here. The end product of the product by process limitation is a catheter with a lumen, there is no salt being claimed and feels that the applicant is reading limitations into the steps. The applicant also failed to come forward with evidence establishing a difference between the claimed product and the prior art product.

With regards to claim 22 in view of Bresnaham et al. in view of Loubser and the argument on page 6 of the brief, applicant once again is reading limitations into the claims. Claim 22 never recited the balloon as the heat exchange element. Claim 26 discloses the use of a balloon as the heating exchange element. In Bresnaham et al. in view of Loubser the balloon (122 – figure 1) of Bresnaham et al. is the heat exchange element and the fluid that passes through the balloon will act as a heat exchange fluid that can absorb or release heat depending on the temperature of the fluid.

Bresnaham et al. discloses that the balloon inflation lumen (114 – Column 11, line 5-25) is connected to a syringe or balloon inflation device (both can be interpreted as a pump), but never recites the flow rate of the pump. The examiner maintains that Bresnaham et al. could be used between 150-450 milliliters but never positively recites the specific rate, so the examiner found Loubser which discloses a pump that was used within that specific rate, thus making it an obvious combination to try the pump of Loubser with the pump of Bresnaham. Loubser also discloses a benefit of using a flow rate between 200-750 milliliters per minute on Column 12, lines 1-20. Therefore it would have been obvious to use the pump Loubser at the specific rate because of the added benefit of less damage to the patient.

With regards to Williams et al. the applicant once again is reading limitations into the claims and failing to give the proper scope to prior art. On Column 13, lines 1-7 Williams discloses the use of pumps to control the fluid flow and that with the teachings of Loubser (the specific rate and benefit of using those pumps) would have made it obvious to combine the device of Williams with the teachings of Loubser.

With regards to injection caps claim 8, both prior art references teach the proximal lumens being Luer locked thus having injection caps connected to them see Williams Column 11, lines 47-51 and Bresnaham et al. Column 11, lines 5-28. With regards to the temperature of the heating and cooling elements, it's well known in the art and is discussed in Williams, and Loubser as well as the references that are incorporated herein by references to them. With regards to the balloon length Williams discloses balloon length in Column 5, lines 47-56 as well as thickness and conductivity and material of the balloon, since the material of the balloons seem to be the same. With regards to the balloon order and diameter Bresnaham et al. discloses this in Column 18 lines 6-40.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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/Matthew F DeSanto/

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